

1.84(p) (5) .

Finally, Applicants proffer an amended specification to be submitted at a later time during prosecution.

Accordingly, Applicants respectfully request the Examiner to enter the amendments to the claims and drawings and to reconsider and allow all claims pending in this application in view of the amendments and following remarks.

**1. Rejection of claim 1 under 35 U.S.C. 102(a)**

The Office Action rejects claim 1 under 35 U.S.C. §102 (a) as being anticipated by "Creating Cataract in a Pig Eye" ("Sugiura et al."). The Office Action states:

Sugiura discloses a model of an eye with cataract comprising a pig's eye which has hardening chemicals injected into the lens.

Applicants respectfully traverse the rejection because Sugiara et al. is not a proper 102(b) reference. In particular, Sugiara et al. does not teach each and every claimed limitation insofar as no disclosure relates to injecting self-hardening type chemicals into a pig's eye.

Turning to the rule, the Federal Circuit has spoken clearly and at some length on the question of anticipation. Anticipation requires that **each and every** element of the claimed invention be disclosed in a **single** prior art reference.

Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Those elements must be **expressly** disclosed as in the claim. In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990).

The prior art reference must also be enabling, thereby placing the allegedly disclosed matter in the possession of the public. In re Brown, 329 F.2d 1006, 1011, 241 USPQ 245, 249 (C.C.P.A. 1964). In order to accomplish this, the reference must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it pertains could construct and use it. Id. at 250.

In the present application, presently pending claim 1 recites a pig's eye which is prepared by injecting self hardening type chemicals into a crystalline lens capsule of said pig's eye. On the other hand, Sugiara et al. provides absolutely no teachings relating to a self-hardening type chemical. All Sugiara et al. teaches is hardening a lens nuclei by reducing the elasticity of the anterior capsules by injecting the mixture of formalin and alcohol (ethanol or 2-propanol or both) into the lens.

Formalin hardens the crystalline proteins in the lens by denaturing the lens proteins. In contrast, the presently claimed invention uses self hardening chemicals which do not

denature and harden the crystalline proteins in the eye. The desirable feature of injecting self hardening agents rather than denaturing chemical is that the lens is not chemically altered. For example, when formalin is injected, the lens takes on a cloudy nature and hardens excessively.

Therefore, a cataract surgery model containing self hardening agents such as claimed by presently pending claim 1 retains a more lifelike texture and appearance. Clearly, the benefits and limitations of a more lifelike model can be seen as it relates to the art of models for cataract surgeries. Since all the claimed limitations are not taught by Sugiara et al. the presently claimed invention is not anticipated by Sugiara et al.

Accordingly, Applicants respectfully submit that the presently claimed invention is novel over the cited reference and respectfully request the Examiner to reconsider and withdraw the 102(a) rejection.

**2. Rejection of claims 2, 3 and 5 under**  
**35 U.S.C. 103(a)**

The Office Action rejects claims 2, 3 and 5 under 35 U.S.C. §103(a) as being unpatentable over "Creating Cataract in a Pig Eye" ("Sugiura et al."). The Office Action states:

While Sugiura does not disclose that the lens capsule is empty as claimed in claims 2 and 3, injecting chemicals into an empty lens capsule would have been obvious to one

of ordinary skill in the art as an aesthetic choice of design and for the purpose of allowing the user to simulate a cataract solely using chemicals. Also, although the location of the injection of claim 5 is not disclosed by Sugiura, the claimed location does not appear to yield any unexpected advantages over the location disclosed by Sugiura, and thus would also have been obvious to one of ordinary skill in the art as an aesthetic choice of design.

Applicants respectfully traverse this rejection because the Office Action fails to establish all three prongs necessary for a *prima facie* case of obviousness. The Office Action also fails to provide any convincing line of reasoning which would lead the ordinarily skilled artisan to modify the references to derive the subject matter as defined in the subject claims. In particular, nowhere does Sugiara et al. teach the use of self hardening chemical agents or injecting said chemicals into an empty lens capsule.

The Federal Circuit ruled that a *prima facie* case of obviousness must establish: (1) some suggestion or motivation to modify the references; (2) a reasonable expectation of success; and 3) that the prior art references teach or suggest all claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the

references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

In the present application, presently pending claims 2, 3 and 5 recite a pig's eye which is prepared by injecting self hardening type chemicals into an empty lens capsule of said pig's eye. Nowhere does Sugiara et al. teach the self hardening agents much less injection of said agents into an empty lens capsule.

In particular, and as provided *supra*, Sugiara et al. merely teaches hardening the crystalline proteins in the lens with formalin. However, the presently claimed invention of claims 2, 3 and 5 recite an **empty** lens. Formalin cannot harden the lens if the lens does not contain crystalline proteins.

In contrast, the self hardening agents of the presently claimed invention can be used to form a false nucleus in the lens capsule. By injecting the self hardening agents, the lens capsule is enucleated from the corpus vitruem, thereby forming a cost effective and cheap alternative to non-nucleated lenses.

Regarding the Office Action assertion that the claimed location of the injection of claim 5 is a mere aesthetic design

choice, Applicants note that claim 5 depends from claim 1. Therefore, claim 5 incorporates all the limitations of claim 1 thereby obviating any argument directed to a limitation regarding an injection location.

Clearly, each and every claimed limitation is not taught by Sugiara et al. Therefore, a *prima facie* case of obviousness has not been established. Again, as stated *supra*, formalin hardens the crystalline proteins in the lens by denaturing the lens proteins in contrast to the presently claimed self hardening chemicals. Clearly, the desirable feature is that the lens is not chemically altered.

Accordingly, Applicants respectfully submit that the presently claimed invention is unobvious over the cited reference and respectfully request the Examiner to reconsider and withdraw the 103(a) rejection.

**3. Rejection of claims 6-8 under**  
**35 U.S.C. 103(a)**

The Office Action rejects claims 6-8 under 35 U.S.C. §103(a) as being unpatentable "Creating Cataract in a Pig Eye" ("Sugiura et al.") in view of Wilder, NCSU Chemical Engineering ("Wilder"). The Office Action states:

Crating Cataract discloses all of the limitations of claims 5-7 with the exception of the use of debenzylidene sorbitol.

Dibenzylidene sorbitol is a known gelling agent which forms three dimensional fibrillar networks in organic substances as disclosed by Wilder. It would have been obvious to one of ordinary skill in the relevant art to modify the model disclosed by Creating Cataract by providing dibenzylidene sorbitol for the purpose of hardening the eye to produce a simulated cataract.

Applicants respectfully traverse this rejection because Sugiara et al. does not teach each and every claimed limitations as is asserted by the Office Action. Even assuming *arguendo* a *prima facie* case of obviousness has been established, the Office Action fails to provide any convincing line of reasoning which would motivate a person of ordinary skill in the art to inject dibenzylidene sorbitol into a pig's eye.

The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

In the present application, presently pending claims 6 and 8 contain the limitations of independent claims 1 and 3. As discussed *supra*, each and every claimed limitation is not present in the primary reference Sugiara et al. Moreover, the Office Action also fails to provide any convincing line of reasoning which would lead the ordinarily skilled artisan to modify the references to derive the subject matter as defined in

the subject claims.

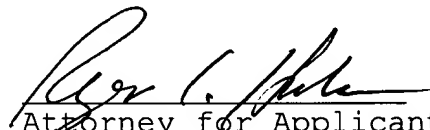
Accordingly, Applicants respectfully submit the presently pending claims are unobvious over the cited reference and request that the Examiner reconsider and withdraw the rejection against the presently pending claims under 35 U.S.C. §103.

### **CONCLUSION**

In light of the foregoing, Applicants submit that the application is now in condition for allowance. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of the pending claims and allow the pending claims. Favorable action with an early allowance of the claims pending is earnestly solicited.

Respectfully submitted,

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# Appendix A

Fig.1

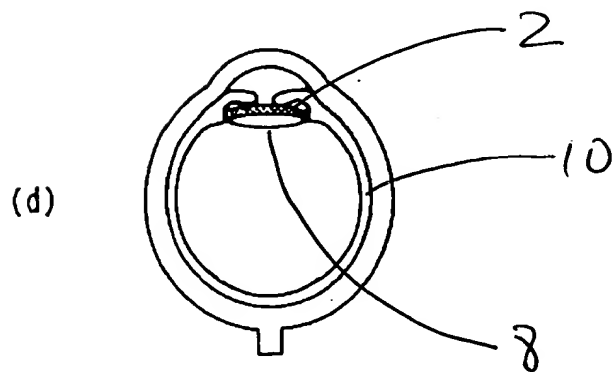
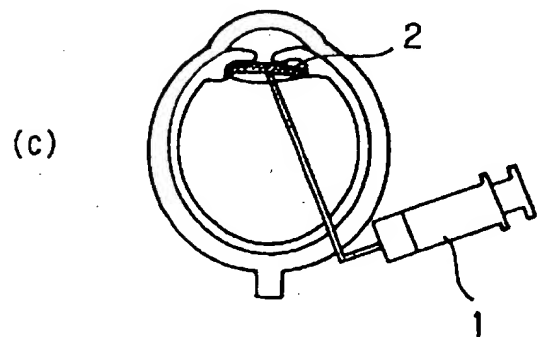
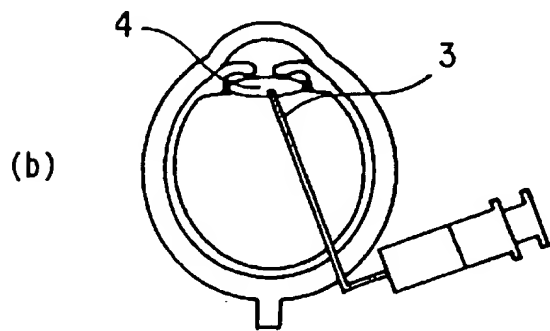
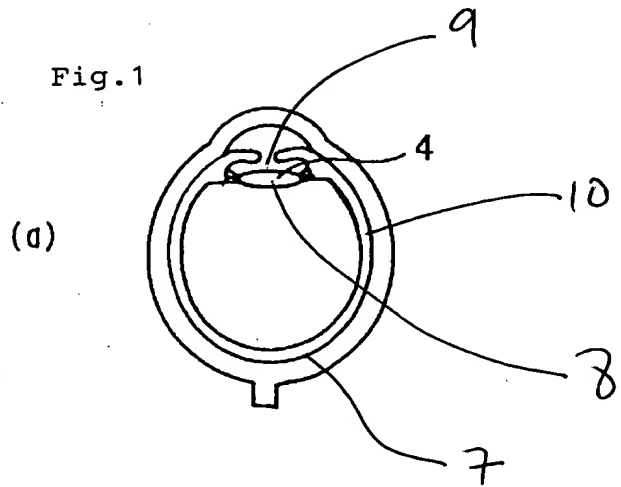
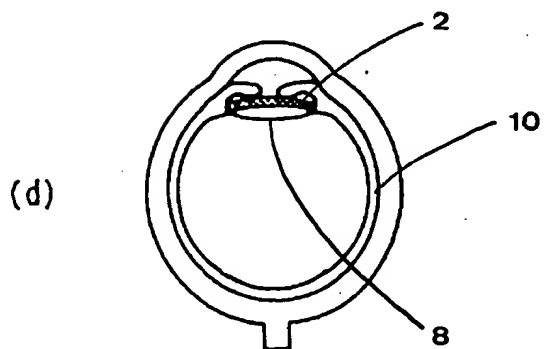
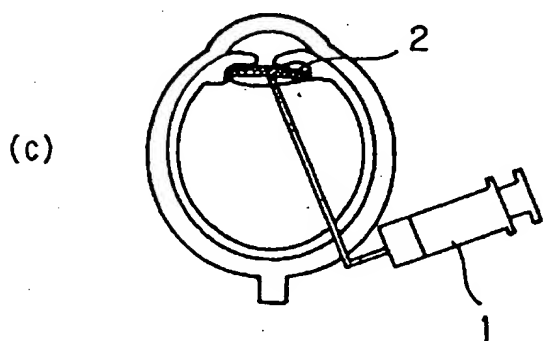
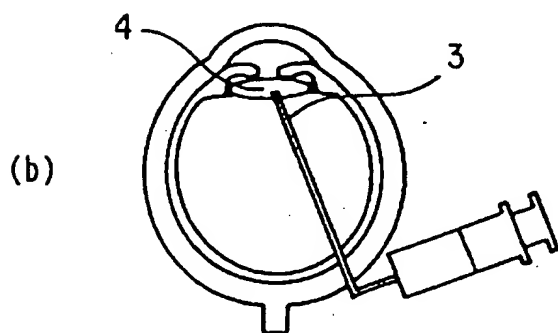
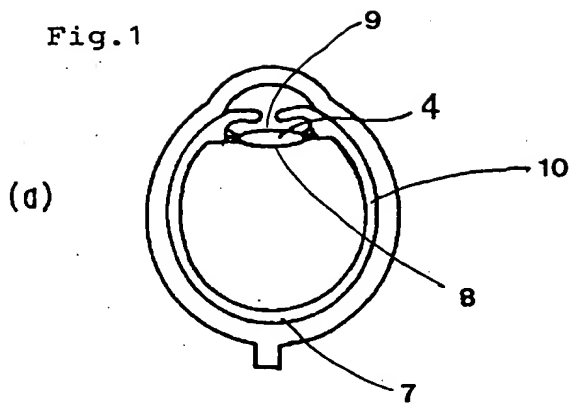




Fig.1





ATTORNEY'S DOCKET TAN-285  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: )  
 ) Group Art Unit: 3712  
UMEYAMA; NAKAKI )  
 ) Examiner: K. FERNSTROM  
Serial No. 09/834,886 )  
 )  
Filed: April 16, 2001 )

For: **A MODEL FOR TRAINING OF SURGICAL OPERATION OF CATARACT**

Appendix C

Please amend the following claims as indicated in the  
following marked-up copy of the claims.

RECEIVED  
AUG 26 2002  
TECHNOLOGY CENTER R3700

1. (Once Amended) A model for [surgical operation for an eye  
with] cataract surgery, comprising:

a pig's eye which is prepared by injecting self hardening type  
chemicals into a crystalline lens capsule of said pig's eye.

2. (Once Amended) [A] The model for [surgical operation for  
an eye with] cataract surgery of claim 1, [comprising pig's eye  
which is prepared by injecting self hardening type chemicals into  
an empty] wherein said crystalline lens capsule of said pig's eye  
is empty.

3. (Once Amended) A model for [surgical operation for an eye

with] cataract surgery [,] in the corpus vitreum , wherein [of which] a false nucleus of a cataract is prepared by injecting self hardening type chemicals into an empty crystalline lens capsule of a pig's eye [is existing].

5. (Once Amended) The model [of eye surgical operation for an eye with] for cataract surgery of [in accordance with] claim 1, [characterizing] wherein said self hardening type chemicals [is] are injected from the posterior pole of [eyeball of] said pig's eye.

6. (Once Amended) The model for [surgical operation for an eye with] cataract surgery of [in accordance with] claim 1, wherein the self hardening type chemicals comprise a composition [mainly comprising] of dibenzylidenesorbitol.

7. (Deleted)

8. (Once Amended) The model for [surgical operation for an eye with] cataract surgery of [in accordance with] claim 3, wherein the self hardening type chemicals comprise a composition mainly comprising dibenzylidenesorbitol.

9. (New) The model for cataract surgery of claim 1, wherein

said self-hardening type chemicals is selected from the group  
consisting of dibenzylidenesorbitol, polyhydric alcohol,  
methylbenzaldehyde, ethyl benzaldehyde, xylitol, and  
dibenzylidenesorbitol.



ATTORNEY'S DOCKET TAN-285  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

UMEYAMA; NAKAKI

Serial No. 09/834,886

Filed: April 16, 2001

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Group Art Unit: 3712

Examiner: K. FERNSTROM

*Amend/figo*  
*# 5/B*  
*B. Ross*  
*8/28/02*

For: **A MODEL FOR TRAINING OF SURGICAL OPERATION OF CATARACT**

Appendix D

Please amend the following claims as indicated in the following clean copy of the claims.

**RECEIVED**  
**AUG 26 2002**  
TECHNOLOGY CENTER R3700

*Sub D7*

*B1*

1. (Once Amended) A model for cataract surgery, comprising:  
a pig's eye which is prepared by injecting self hardening type  
chemicals into a crystalline lens capsule of said pig's eye.

2. (Once Amended) The model for cataract surgery of claim 1,  
wherein said crystalline lens capsule of said pig's eye is empty.

3. (Once Amended) A model for cataract surgery in the corpus  
vitreum, wherein a false nucleus of a cataract is prepared by  
injecting self hardening type chemicals into an empty crystalline  
lens capsule of a pig's eye.

Sub D7  
B2 5. (Once Amended) The model for cataract surgery of claim 1, wherein said self hardening type chemicals are injected from the posterior pole of said pig's eye.

Sub D7  
B3 6. (Once Amended) The model for cataract surgery of claim 1, wherein the self hardening type chemicals comprise a composition of dibenzylidenesorbitol.

7. (Deleted)

Sub D7  
B4 8. (Once Amended) The model for [surgical operation for an eye with] cataract surgery of [in accordance with] claim 3, wherein the self hardening type chemicals comprise a composition mainly comprising dibenzylidenesorbitol.

Sub D7  
B5 9. (New) The model for cataract surgery of claim 1, wherein said self-hardening type chemicals is selected from the group consisting of dibenzylidenesorbitol, polyhydric alcohol, methylbenzaldehyde, ethyl benzaldehyde, xylitol, and dibenzylidenesorbitol.